

Templates and core content for the patient information leaflet and patient-held monitoring and dosage record

These documents can support NHS organisations and professionals in the safer management and administration of oral methotrexate. The templates contain the core content that should be in the patient information leaflet and the patient-held monitoring and dosage record. The documents can have information added for local preferences, style and approach. However, none of the core content should be removed. You may want to consider producing them in conjunction with other NHS organisations in your area and putting the information on your website.

All the information reflects what patients and professionals have told the NPSA they need to support them at the outset and during the course of treatment.

General points, which apply to both the patient information leaflet and the patient-held monitoring and dosage record, are below. More detailed information for each of the two documents is provided in the following pages.

Content presentation guidelines

- Use a font that is easy to read such as Ariel or Frutiger
- The font size should be 14 point for headings and 12 point for text
- There should be a 1½ line spacing
- Headings should be in bold and text in plain
- Headings will stand out more if they are in a different colour to the rest of the text

Layout and design

You can download PDF files of the recommended content on the NPSA website at www.npsa.nhs.uk/advice and this includes a Welsh translation of the patient information leaflet.

Testing and evaluation with patients and clinicians has shown that it is most effective to produce:

- the patient information leaflet as an A4 (297x210mm) four-page document
- the patient-held monitoring and dosage record as an A6 (149x105mm) booklet with multiple pages of the monitoring tables and pages for recording dosage regimes. These are shown on the following pages.

Notice for clinicians

The release date of the information leaflet and patient-held monitoring and dosage record is 29 July 2004. Clinicians should ensure that they take into account any relevant developments in clinician practice and knowledge since the release date.

In the event that a clinician has any comments or feedback about this patient-held monitoring and dosage record, they should contact Wendy Harris of the National Patient Safety Agency at wendy.harris@npsa.nhs.uk

Contact details for the healthcare staff looking after you

This booklet belongs to:

Hospital consultant:

Hospital:

Specialist nurse:

GP surgery address:

GP surgery telephone:

Community pharmacy:

Pharmacy address:

Pharmacy telephone:

If found, please return this booklet to:

Choose a day of the week to take your oral methotrexate and stick to it

Write down your chosen day of the week below and this will help you remember which day to take your dose.

Day of the week for taking oral methotrexate:

If you miss your dose on your normal day, don't worry you can take it on one of the two following days.

For example, if your normal day for taking your dose is Thursday, you can take it on either Friday or Saturday.

Do not take the dose if you are three or more days late. A flare up of the disease during this time is unlikely.

In both cases, take your next dose on your usual day.

Why you need regular blood tests

It is important that you do not miss your blood test. You must not take methotrexate unless you are having regular blood tests every 4 to 12 weeks. They tell your doctor how well methotrexate is working.

Methotrexate reduces the production of blood cells and this can make you more vulnerable to infections. Blood tests will show if you are developing any side effects. If your blood, liver, kidneys or lungs are being affected, your treatment will be changed or stopped immediately.

Avoid having blood tests done directly after taking your dose as this can mask any changes.

Keeping this booklet up-to-date will help you, your doctor and pharmacist know that the dose is right for you and not adversely affecting your body. Your doctor may increase or decrease the number of tablets you take at each dose depending upon the results of your tests.

Things you must tell medical staff

If you need emergency treatment, the medical staff helping you will need to know that you are taking oral methotrexate.

Over-the-counter drugs

The information in this diary will help a pharmacist determine if over-the-counter drugs are suitable for you.

Taking other medicines

Always check with your doctor or pharmacist before taking any other medicine. This includes medicines you can buy at a garage, newsagent, supermarket or chemist such as aspirin, paracetamol, other painkillers and medicines for coughs, colds and flu. This equally applies to herbal and alternative remedies. These can react with methotrexate and affect your treatment.

Also, the symptoms you are trying to treat may be a sign of methotrexate not working safely for you. It is important for your doctor or pharmacist to know so they can help you. Keep a record of any symptoms and discuss them with your doctor.

NHS Direct

You must tell NHS Direct you are taking oral methotrexate before seeking their help.

If you have any of the following, tell your doctor immediately

Infections

- infections including fever, chills or a sore throat
- unexplained skin rash, ulcerations or soreness of skin
- yellowing of the skin or generalised itching
- bleeding gums, black tarry stools or unexpected bleeding or bruising
- chest pain, difficulty breathing or a dry, persistent cough
- sore mouth or mouth ulcers
- severe and continuing diarrhoea, vomiting or stomach pains
- vaginal inflammation or ulcers

Chicken pox and shingles

If while you are taking methotrexate you develop chicken pox or shingles and it seems to be severe, you should see your doctor as you may need special treatment.

See your doctor if you develop any new symptoms after starting methotrexate.

Other advice

Drinking alcohol

Alcohol can react with methotrexate so it is advisable not to drink. However, an occasional drink may not be expected to cause significant side effects. Your doctor can give you more information and advice about this.

Food

Food made from unpasteurised milk, such as soft cheese and uncooked meats such as pâté, may be a source of bacteria which could increase your risk of infection. Read food labels carefully, and avoid eating these types of food.

Having a baby

Methotrexate can reduce fertility in men and women. It can also damage an unborn child. Women should not take methotrexate if they are pregnant or breastfeeding. It is recommended that you wait six months after finishing your treatment, before trying to become pregnant. You should talk to your doctor or nurse about effective contraception. It is recommended that men wait six months after finishing their treatment, before trying to father a child as sperm can be affected.

Vaccinations

Your doctor or nurse should not offer you any immunisation injections that have any of the live vaccines such as polio and rubella (German measles). However, flu vaccines are safe.

Antibiotics

Some antibiotics affect the way that methotrexate works. Your doctor should not prescribe any that effect methotrexate; you should not take any Trimethopin, Co-trimoxazole or Septrin® whilst taking methotrexate.

Record of your dose

Keep a record of your dose by filling in details of your dose and the number of tablets you should take. If your dose changes, for example after a blood test, record the new dose here.

Take this new dose, and not the dose shown on the bottle or carton label.

Show this record to your pharmacist each time you receive some more methotrexate tablets.

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Monitoring results

The person responsible for prescribing/monitoring your methotrexate can help you complete this record

Test date

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Weekly dose (mg)

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Test	Normal Range
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Hb	male	13.5–17.5g/dl
	female	12–16g/dl

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MCV	80–100fl
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WBC	4.0–11.0x10 ⁹ /l
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Platelets	150–400x10 ⁹ /l
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Neutrophils	2.0–7.5x10 ⁹ /l
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Lymphocytes	1.5–4.0x10 ⁹ /l
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ALT	0–37u/l
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Alk phos.	30–130u/l
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CRP	0–10mg/l
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ESR	varies for each individual
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Urea	2.5–8.0mmol/l
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Creatinine	60–125μmol/l
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Next test date

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What the terms mean

Hb:	The oxygen carrying protein pigment in the blood, specifically in red blood cells.
MCV:	The average volume of a red blood cell.
WBC:	White blood cells.
Platelets:	an irregular, disc-shaped element in the blood that assists in blood clotting.
Lymphocytes:	a small white blood cell that plays a large role in defending the body against disease. They are responsible for immune responses.
Neutrophils:	type of white blood cell filled with enzymes used to kill and digest micro-organisms.
ALT:	an enzyme normally present in the liver and heart cells that is released into the blood stream when the liver or heart is damaged. Rising blood ALT levels may indicate liver damage.

- ALK phos:** an enzyme made in the liver which is usually released into the blood during injury. Abnormally high levels may indicate liver damage.
- CRP:** a plasma protein that rises in the blood with the inflammation of certain conditions.
- ESR:** a blood test that detects and monitors inflammation in the body. The rate increases with more inflammation.
- Urea:** a substance normally cleared from the blood by the kidney. Increased blood levels of urea indicate a problem with kidney function.
- Creatinine:** a substance normally cleared from the blood by the kidney. Increased blood levels of creatinine indicate a problem with kidney function.

Important notice

This patient-held monitoring and dosage record has been compiled after consideration of the information available by the National Patient Safety Agency as at July 2004. It is not intended to be exhaustive and should not be used as a substitute for consulting your clinician on any particular issue. The National Patient Safety Agency makes no representations, warranties or guarantees as to the accuracy, completeness or adequacy of any of the content of this patient-held record and cannot be held responsible for any liability, loss or damage whatsoever which may arise from the use of, or reliance upon, this patient-held monitoring and dosage record, except as may otherwise be required by law.